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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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David G. Quinn

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EXAMINER

SCHMIDT, EMILY LOUISE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,674	QUINN, DAVID G.	
	Examiner	Art Unit	
	Emily Schmidt	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2010 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 17, 2010 has been entered.

Drawings

2. The drawings are objected to because they appear to incorporate new matter into the specification, see rejection under 35 USC 112 below. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not

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accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The amendment filed March 23, 2010 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The gastric suction and feeding lumens as indicated in the amended drawings and specification were not previously disclosed as such.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

4. Claims 46-48 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 40-42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 40 recites a stylet while claim 46 recites a stiffener. The only slight difference in wording renders these claims to be so close in content that they cover the same thing.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 40-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 40, 46, and 51 recite that the mid-port bolus has a side port adapted to communicate with the patient's stomach with a gastric suction lumen and a passage connecting the feeding lumen of the first and second tube. The specification at the time of filing does not appear to explicitly disclose that the lumen connected to the side port is used for gastric suction as opposed to feeding.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 40-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. The term "very flexible" in claims 40-51 is a relative term which renders the claim indefinite. The term "very flexible" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would

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not be reasonably apprised of the scope of the invention. Thereby, the flexibility of the catheter tube is rendered indefinite.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 40, 41, 43, 46, 47, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson Jr. (US 5,318,530) in view of Andersen et al. (US 4,594,074), Andersen (US 6,511,474), and Ferguson et al. (US 5,637,086).

With regard to claims 40, 41, 46, and 47, Nelson Jr. teaches a naso-enteral feeding catheter and stylet/stiffener assembly for jejunal insertion of the catheter through a patient's nares, stomach, pylorus and duodenum into the jejunum (Col. 1 lines 9-17), comprising: (a) an elongated, very flexible, first catheter tube containing urethane (Figs. 1 and 2 taken to extend from the end at 11 to 15E, Col. 4 line 16), said first catheter tube having a proximal end and a distal end and including a naso-enteral feeding lumen and a separate gastric suction lumen extending through said first catheter tube (Fig. 2 feeding lumen 28 suction lumen 25); (b) an elongated, very flexible, second catheter tube containing urethane (Figs. 1 and 2 taken to extend from the end at 15E to end at 12, Col. 4 line 16), said second catheter tube having a proximal end and a distal end and including a naso-enteral feeding lumen extending through said second catheter tube (Fig. 3 lumen 28).

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Nelson Jr. discloses a bolus (Fig. 1 member 17) but does not specifically disclose a mid-port and tip bolus. However, Andersen et al. '074 teach using a bolus feature around an ingress/egress port in a feeding tube is beneficial as it prevents blockages and provides for uniform flow (Col. 3 lines 60-63). The bolus member 18 of Andersen et al. '074 can be used as a connection between two members (Fig. 7). Andersen '474 teach that the lumens can continue through the bolus (Fig. 3) and that the tip of the device should be blunt to maintain minimal resistance while the device is inserted into the body (Col. 6 lines 5-8). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to separate the catheter of Nelson Jr. and use a bolus with a side port in the device of Nelson Jr. in the area of suction holes 15 and to continue the feeding lumen through the bolus to connect with the feeding catheter portion and a second blunt bolus on the distal end 12 with a port for feeding fluid of Nelson Jr. because it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin V. Erlicnman*, 168 USPQ 177, 179 and Andersen et al. '074 and Andersen '474 teach boluses which are beneficial to use around the ingress/egress ports of a feeding catheter because they prevent blockages and provide for uniform flow.

Nelson Jr. teaches that the device can be inserted over a guidewire, a guidewire is taken to effectively be a stylet/stiffener, but does not disclose first and second stylets. However, Ferguson et al. teach using multiple stylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed (Col. 4 lines 35-37). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use two guidewires/stylets in the device of Nelson Jr. because Ferguson et al. teach using multiple stylets

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within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed. Further, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a second stylet, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

With regard to claims 43 and 49, see Nelson Jr. Col. 6 lines 20-23.

12. Claims 42, 44, 45, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson Jr. (US 5,318,530), Andersen et al. (US 4,594,074), Andersen (US 6,511,474), and Ferguson et al. (US 5,637,086) as applied to claim 40 above, and further in view of Pozzo (US 5,092,847).

With regard to claims 42 and 48, Nelson Jr. teaches an assembly substantially as claimed. Nelson Jr. does not disclose the French size of the catheter. However, Pozzo teaches using a feeding tube with an 8 Fr diameter as being a known commercially available feeding tube (Col. 4 lines 25-30). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an 8 Fr tube in the device of Nelson Jr. because Pozzo teaches that such is an effective size for a tube used in the gastrointestinal system. Nelson Jr. teaches the aspiration lumen to be larger than the feeding lumen (Fig. 2) but does not specifically disclose the catheter tube being a 5 Fr size tube. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to use an 8 Fr and 5 Fr tube because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore,

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would have expected the Applicant's invention to perform equally well with the tube of Nelson Jr. because it still allows for adequate fluid delivery and feeding.

With regard to claims 44 and 45, Nelson Jr. teaches an assembly substantially as claimed. Nelson Jr. does not disclose details of the stylet. However, Pozzo teaches feeding catheter tube guided by a twisted wire stylet with a stylet fitting (Fig. 3 stylet 32 fitting 34, claim 1 last two paragraphs) which fits into a sleeve fitting of the catheter (Fig. 1 fitting generally indicated at 25). This stylet is beneficial as it can provide the needed stiffness and not puncture the catheter (Col. 3 lines 6-10). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a stylet as in Pozzo in the device of Nelson Jr. because Nelson Jr. already teaches guiding the catheter over a guidewire and the stylet of Pozzo is used with feeding tubes and is beneficial because it will not pierce the feeding tube,. As rejected above with regard to Ferguson et al. it would be obvious to use two stylets as in Pozzo with the device of Nelson Jr. The sleeve of the second stylet is taken as portion 40 (Fig. 3). The stylet of Pozzo includes a lumen through the stylet so that when replicated one stylet can fit through the other.

13. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson Jr. (US 5,318,530), Andersen et al. (US 4,594,074), Andersen (US 6,511,474), and Ferguson et al. (US 5,637,086) as applied to claim 47 above, and further in view of Bengmark (WO 98/33469).

With regard to claim 50, Nelson Jr. teaches an assembly substantially as claimed. Nelson Jr. does not disclose a coiled section adjacent the tip bolus. However, Bengmark teaches it is known in the art to use a normally coiled section adjacent the tip bolus of a catheter inserted into

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the small intestine (example in Fig. 3) because it helps the catheter retain its location within the intestine (Pg. 1 lines 28-30, Pg. 2 lines 4-7).

14. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson Jr. (US 5,318,530) in view of Pozzo (US 5,092,847), Andersen et al. (US 4,594,074), Andersen (US 6,511,474), and Ferguson et al. (US 5,637,086).

With regard to claim 51, Nelson Jr. teaches a naso-enteral feeding catheter and stylet/stiffener assembly for jejunal insertion of the catheter through a patient's nares, stomach, pylorus and duodenum into the jejunum (Col. 1 lines 9-17), comprising: (a) an elongated, very flexible, first catheter tube containing urethane (Figs. 1 and 2 taken to extend from the end at 11 to 15E, Col. 4 line 16), said first catheter tube having a proximal end and a distal end and including a naso-enteral feeding lumen and a separate gastric suction lumen extending through said first catheter tube (Fig. 2 feeding lumen 28 suction lumen 25); (b) an elongated, very flexible, second catheter tube containing urethane (Figs. 1 and 2 taken to extend from the end at 15E to end at 12, Col. 4 line 16), said second catheter tube having a proximal end and a distal end and including a naso-enteral feeding lumen extending through said second catheter tube (Fig. 3 lumen 28); (c) the overall combined length of the tubes being at least 60 inches (Col. 6 lines 20-23). Nelson Jr. does not disclose the French size of the catheter. However, Pozzo teaches using a feeding tube with an 8 Fr diameter as being a known commercially available feeding tube (Col. 4 lines 25-30). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use an 8 Fr tube in the device of Nelson Jr. because Pozzo teaches that such is an effective size for a tube used in the gastrointestinal system. Nelson Jr.

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teaches the aspiration lumen to be larger than the feeding lumen (Fig. 2) but does not specifically disclose the catheter tube being a 5 Fr size tube. It would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made use an 8 Fr and 5 Fr tube because Applicant has not disclosed that such a size provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the tube of Nelson Jr. because it still allows for adequate fluid delivery and feeding.

Nelson Jr. discloses a bolus (Fig. 1 member 17) but does not specifically disclose a mid-port and tip bolus. However, Andersen et al. '074 teach using a bolus feature around in ingress/egress port in a feeding tube is beneficial as it prevents blockages and provides for uniform flow (Col. 3 lines 60-63). The bolus member 18 of Andersen et al. '074 can be used as a connection between two members (Fig. 7). Andersen '474 teach that the lumens can continue through the bolus (Fig. 3) and that the tip of the device should be blunt to maintain minimal resistance while the device is inserted into the body (Col. 6 lines 5-8). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to separate the catheter of Nelson Jr. and use a bolus with a side port in the device of Nelson Jr. in the area of suction holes 15 and to continue the feeding lumen through the bolus to connect with the feeding catheter portion and a second blunt bolus on the distal end 12 with a port for feeding fluid of Nelson Jr. because it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin V. Erlicnman*, 168 USPQ 177, 179 and Andersen et al. '074 and Andersen '474 teach boluses which are beneficial to use around the

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ingress/egress ports of a feeding catheter because they prevent blockages and provide for uniform flow.

Nelson Jr. teaches that the device can be inserted over a guidewire, a guidewire is taken to effectively be a stylet/stiffener, but does not disclose first and second stylets. However, Ferguson et al. teach using multiple stylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed (Col. 4 lines 35-37). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use two guidewires/stylets in the device of Nelson Jr. because Ferguson et al. teach using multiple stylets within a catheter inserted to various lengths within the catheter to vary the stiffness of the catheter as needed. Further, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to add a second stylet, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art, *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Nelson Jr. and Ferguson et al. do not disclose details of the stylet. However, Pozzo teaches feeding catheter tube guided by a twisted wire stylet with a stylet fitting (Fig. 3 stylet 32 fitting 34, claim 1 last two paragraphs) which fits into a sleeve fitting of the catheter (Fig. 1 fitting generally indicated at 25). This stylet is beneficial as it can provide the needed stiffness and not puncture the catheter (Col. 3 lines 6-10). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a stylet as in Pozzo in the device of Nelson Jr. because Nelson Jr. already teaches guiding the catheter over a guidewire and the stylet of Pozzo is used with feeding tubes and is beneficial because it will not pierce the feeding tube. As rejected above with regard to Ferguson et al. it would be obvious to use two

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stylets as in Pozzo with the device of Nelson Jr. The sleeve of the second stylet is taken as portion 40 (Fig. 3). The stylet of Pozzo includes a lumen through the stylet so that when replicated one stylet can fit through the other.

Response to Amendment

15. The amendments to the claims have been entered.

Response to Arguments

16. Applicant's arguments filed December 17, 2010 have been fully considered but they are not persuasive. The Examiner maintains the objections and rejections regarding the gastric and feeding lumens, as originally filed the specification does not disclose which lumens are used for which purpose. The Examiner maintains that Nelson in view of Anderson et al. '074 teach placing the bolus at the port of Nelson and separating it into two tubes for flow benefits as recited above. Regarding Andersen '474, the Examiner finds it is relevant as it is drawn to providing a bolus. Regarding Ferguson et al, it is not relied on to teach a bolus or side port, but rather a stylet. Regarding Pozzo, the Examiner maintains that Pozzo teach a stylet which is inserted into a feeding tube and it would be obvious to use multiple stylets in view of Ferguson et al.. Regarding Bengmark, Bengmark is not relied upon to teach the tubes connected by a bolus.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/
Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767